

# इंटरनेट

# मानक

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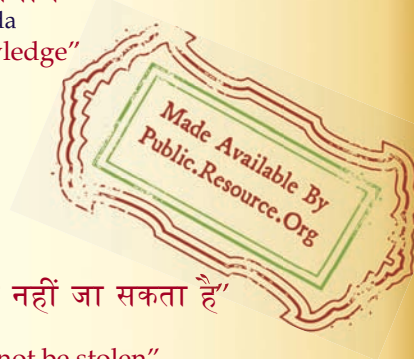
IS 3055-2 (2004): Clinical thermometers, Part 2: Enclosed scale type-Specification [MHD 10: Medical Laboratory Instruments]



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Bhartrhari—Nitiśatakam

“Knowledge is such a treasure which cannot be stolen”



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भारतीय मानक  
डाक्टरी थर्मामीटर  
भाग 2 बन्द स्केलनुमा  
( तीसरा पुनरीक्षण )

*Indian Standard*

CLINICAL THERMOMETERS  
PART 2 ENCLOSED SCALE TYPE — SPECIFICATION  
( *Third Revision* )

ICS 11.040.55

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**BUREAU OF INDIAN STANDARDS**  
MANAK BHAVAN, 9 BAHADUR SHAH ZAFAR MARG  
NEW DELHI 110002

## FOREWORD

This Indian Standard (Part 2) (Third Revision) was adopted by the Bureau of Indian Standards, after the draft finalized by the Medical Instruments and Disposables Sectional Committee had been approved by the Chemical Division Council.

This standard was first issued in 1965 and covered only solid-stem type clinical thermometer. It was revised in 1977, when it was decided to issue it in two parts; Part 1 covering solid-stem type thermometers only, while (Part 2) issued in 1988 covered enclosed scale type thermometer. The standard was further revised in 2002 with a view to harmonize it with the latest OIML No. 7 and EEC directives No. 76/764/EEC of 27 July, 1986 as well as the *Indian Weight and Measures Act*, 1976. In this revision, the requirements for influence of immersion time and mean depression of zero have been added. The requirements concerning ageing and the instructions for proper use have also been incorporated. One amendment was issued and other was finalized. Subsequently it was felt to revise it further in order to harmonize it with latest OIML and EEC directive.

In this revision, the clinical thermometer of rectal pattern has been deleted, the requirement of Fahrenheit scale has been incorporated, the requirement of capillary tube has been modified in line with BS 6985 : 1989 'Specification for enclosed-scale clinical maximum thermometers (mercury-in-glass)' the clause pertaining to bulb has been deleted since it is drawn from sheath tube.

The responsibility of first official verification as mentioned under 8.2.2 and to mark a recognized mark of the verifying authority as mentioned under 9.2(e) shall be of officers authorized under the provision of *The Standards of Weights and Measures (Enforcement) Act*, 1985.

At present there is no ISO Standard on the subject.

The composition of the Committee responsible for formulation of this standard is given in Annex D.

For the purpose of deciding whether a particular requirement of this standard is complied with, the final value observed or calculated, expressing the result of a test or analysis, shall be rounded off in accordance with IS 2 : 1960 'Rules for rounding off numerical values (*revised*)'. The number of significant places retained in the rounded off value should be the same as that of the specified value in this standard.

# *Indian Standard*

## CLINICAL THERMOMETERS

### PART 2 ENCLOSED SCALE TYPE — SPECIFICATION

### ( Third Revision )

#### 1 SCOPE

This standard (Part 2) specifies requirements and methods of sampling and tests for enclosed scale type, mercury-in-glass clinical thermometers having a maximum indicating device.

#### 2 REFERENCES

The following standards contain provisions, which through reference in this text, constitute provisions of this standard. At the time of publication, the editions indicated were valid. All standards are subject to revision, and parties to agreements based on this standard are encouraged to investigate the possibility of applying the most recent editions of the standards indicated below:

<i>IS No.</i>	<i>Title</i>
2303 (Part 1/Sec 1) : 1994	Grading glass for alkalinity: Part 1 Hydrolytic resistance, Section 1 Hydrolytic resistance of glass grains at 98°C — Method of test and classification ( <i>first revision</i> )
2627 : 1979	Glossary of terms relating to liquid- in-glass thermometers ( <i>first revision</i> )
6274 : 1971	Method of calibrating liquid-in-glass thermometers
8787 : 1977	Principles of design, construction and use of liquid-in-glass thermometers

#### 3 TERMINOLOGY

**3.1** For the purpose of this standard, the definitions given in IS 2627 and the following shall apply.

**3.2 Glass Tubes** — Sheath tubes, capillary tubes and constriction tube.

#### 4 TYPE

The thermometers shall be of the enclosed scale, mercury-in-glass type.

#### 5 TEMPERATURE SCALE

**5.1** The thermometers shall have a translucent strip made of paper, plastic or a material of comparable dimensional stability, graduated in degree Celsius (°C). The thermometers shall have range from 35 to 42°C or 35 to 43°C.

**5.2** In addition, the thermometer may also be graduated in degrees Fahrenheit (°F). The range shall be 94 to 108°F or 94 to 110°F.

#### 6 CALIBRATION

The thermometers shall be calibrated by dipping the thermometer in a vertical position up to the taper of the sheath.

#### 7 REQUIREMENT

##### 7.1 Patterns

The stem of thermometers shall as shown in Fig. 1. The thermometer shall be used in mouth or armpit or groin.

##### 7.2 Materials

###### 7.2.1 Glass Tubing

The sheath tube, capillary tube and constriction tube shall be made from suitable thermometer glass tubing. A taper bulb shall be drawn from the sheath tube, which assures that the depression of zero, determined in accordance with the procedure given in Annex A, does not exceed 0.07°C.

**7.2.2** The types of glass used for the constriction tube, capillary tube and sheath tube shall meet the following requirements:

When the glass is tested for hydrolytic resistance according to IS 2303 (Part 1/Sec1), the quantity of alkali passed into solution for 1 g of glass must correspond to not more than 263.5 µg of Na<sub>2</sub>O.

###### 7.2.3 Thermometric Liquid

The thermometric liquid shall be pure, dry mercury.

##### 7.3 Construction

###### 7.3.1 Sheath

The sheath shall be in alignment with the constriction tube and capillary tube. The thermometer sheath shall be round or oval in shape.

**7.3.1.1** The free end of the sheath shall be finished smooth, preferably hemispherical in shape, as shown in Fig. 1.

###### 7.3.2 Maximum Indicating Device (Constriction)

The thermometer shall have constriction formed on

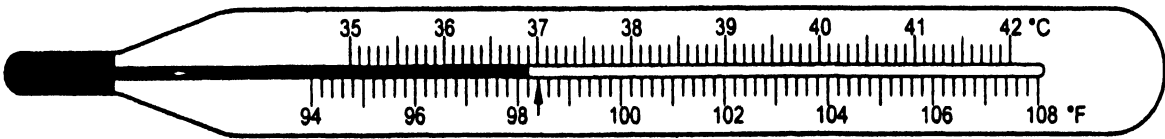


FIG. 1 CLINICAL THERMOMETER, ENCLOSED SCALE TYPE

the constriction tube in order to prevent the mercury returning to the bulb when cooling.

7.3.2.1 The maximum indicating device shall pass the hardness test prescribed in Annex B, when an acceleration of 600 m/s<sup>2</sup> is applied at the closed end of the bulb for a period of 2 min.

7.3.3 Bulb

The bulb drawn from sheath tube shall be gradually tapered with a smoothly rounded end and it shall be in alignment with the body of the thermometer.

7.3.4 Strip Bearing the Scale

The strip bearing the scale shall be directly fixed with the capillary tube and fixed sufficiently firmly in the sheath to prevent any displacement with respect to the tube. The strip shall be so positioned as to ensure that any displacement can be easily detected by means of an indelible mark on the sheath level with numbered scale.

7.3.5 The capillary tube shall be of smooth and uniform bore. The capillary tube shall ensure that the entire length of the liquid column and the meniscus are clearly visible from at least one angle. It shall be prismatic in form and have a magnifying effect or shall be designed as to ensure consistent ease of reading.

7.3.6 The sheath, capillary tube, constriction tube and mercury shall be sufficiently free from entrapped gas, debris and foreign bodies, in order to ensure the correct functioning of the thermometer.

7.4 Dimension

The dimensional and scale requirements for clinical thermometer shall be as given in Table 1.

7.5 Graduation and Numbering

7.5.1 The thermometer scale shall be sub-divided in 0.1°C as shown in Fig. 1.

7.5.2 The graduation lines shall be printed permanently on the strip. They shall be equally spaced and shall be at right angles to the axis of the thermometer.

7.5.3 All graduation lines shall be equal and of uniform thickness of not more than one-fourth of the length of the smallest scale division.

7.5.4 The pattern of graduation and numbering shall be as follows:

- a) Every tenth graduation line shall be a long line (about 2 mm) which shall be numbered;
- b) There shall be a medium line (about 1.5 mm) midway between two consecutive long lines; and
- c) There shall be four short lines (about 1 mm) equally spaced between consecutive medium and long lines.

Table 1 Dimensional and Scale Requirements for Enclosed Scale Clinical Thermometer  
(Clause 7.4)

Sl No.	Particulars	Requirements
(1)	(2)	(3)
i)	Scale range, °C	35 to 42 or 35 to 43
ii)	Scale range, °F	94 to 108 or 94 to 110
iii)	Smallest scale division, °C	0.1
iv)	Smallest scale division, °F	0.2
v)	Overall length, mm, <i>Max</i>	125
vi)	Scale length, mm	40 to 75
vii)	External diameter of sheath (round or oval), mm, <i>Max</i>	12.5
viii)	Bulb length, mm, <i>Max</i> (see Note)	21
ix)	Distance from top of the constriction to the 35°C mark, mm, <i>Min</i>	10
x)	Distance from the highest graduation line to top of sheath, mm, <i>Min</i>	8
xi)	Scale spacing, mm, <i>Min</i>	0.5
xii)	Thickness of strip, mm	0.3 ± 0.1

NOTE — See Fig. 3 of IS 8787.

7.5.5 When the thermometer is held in a vertical position and viewed from the front, the left-hand ends of all the graduation lines shall lie on a imaginary vertical line (see Fig. 1).

7.5.6 The numbers shall be placed along the axis in such a way that extension of the line to which they refer, would bisect them. The numbers shall be placed parallel to the axis of the thermometer.

7.5.7 A distinguishing mark (say, an arrow or a dot) shall be marked at 37.0°C/98.6°F to prominently indicate the normal temperature.

7.5.8 All graduation lines and numbering shall be clearly visible.

8 PERFORMANCE REQUIREMENTS

8.1 Appearance

When heated to 42°C or so, the mercury column shall look like a rectangular strip of uniform width, clarity and brightness throughout.

NOTE — This test takes care of all visual defects, for example, twist in the glass, aberrations, cloudiness, devitrification, etc.

8.2 Ageing and Accuracy

8.2.1 The clinical thermometers shall meet all the requirements after ageing by natural or artificial means. Natural ageing involves holding the thermometers at room temperature for four months after completion of the constriction. Artificial ageing method involves heat treatment of the bulb and constriction of the unfilled thermometer at a temperature and duration to be specified by the manufacturer of the glass tubing.

8.2.2 Clinical thermometers after ageing as per 8.2.1 shall ensure that their accuracy as measured by the method specified in Annex C, shall be as given below for at least one year after the first official verification:

Range, °C	Accuracy, °C
Less than 35.8	± 0.3
Greater than 35.8 but less than 37.0	± 0.2
37.0 to 39.0	± 0.1
Greater than 39.0 to 41.0	± 0.2
Greater than 41.0	± 0.3

8.3 Influence of Immersion Time

If a thermometer at temperature  $t_1$  ( $15^{\circ}\text{C} \leq t_1 \leq 30^{\circ}\text{C}$ ) is suddenly immersed in a well-stirred water bath having a constant temperature  $t_2$  ( $35.5^{\circ}\text{C} \leq t_2 \leq 42^{\circ}\text{C}$ ) and is withdrawn after 20 s, the thermometer reading, after cooling to ambient temperature ( $15^{\circ}\text{C}$  to  $30^{\circ}\text{C}$ ) shall:

- a) comply with maximum permissible error requirements (see 8.2.2), and
- b) not deviate from its stabilized reading for temperature  $t_2$  by more than  $0.005 (t_2 - t_1)$ .

This stabilized reading is the thermometer reading obtained when the thermometer has been cooled to ambient temperature, after reaching complete thermal equilibrium with the water bath at temperature  $t_2$ . This reading must also meet the maximum permissible error requirements stipulated 8.2.2.

NOTE — A free choice of test method is permitted, provided the law of the variation of the indication of the thermometer as a function of immersion time is known.

9 PACKING AND MARKING

9.1 Packing

9.1.1 Clinical thermometers shall be securely packed, individually or collectively, in any manner acceptable to the purchaser, so as to minimize the risk of damage in handling, transport and storage. Special care should be taken to use suitable buffer plugs to protect the tips.

9.1.2 A pamphlet with instructions for proper use shall be provided by the manufacturer with each thermometer. Following cautionary note shall appear in the pamphlet:

Mercury is highly poisonous. In the event of breakage of thermometers, clean the mercury spills immediately. Keep all people and pets away from the spill area. While cleaning, wear rubber gloves, collect the spilled mercury, broken thermometer and other contaminated object into a glass or plastic container and dispose these appropriately. Do not use a vacuum to clean up mercury spill. Any tool used for clean up should be disposed of with the mercury. Do not let mercury go down the sink drain.

9.2 Marking

Each clinical thermometer shall be legibly and indelibly marked on its strip with the following:

- a) Letter °C and °F near the top of the respective scale;
- b) Word 'oral';
- c) An indication of the source of manufacture;
- d) A code number to trace the batch of manufacture; and
- e) A recognized mark of the verifying authority showing the year of initial verification.

9.2.1 BIS Certification Marking

The packages may also be marked with the Standard Mark.

9.2.1.1 The use of the Standard Mark is governed by the provisions of the *Bureau of Indian Standards Act, 1986* and the Rules and Regulations made thereunder. The details of conditions under which the licence for the use of the Standard Mark may be granted to manufacturers or producers may be obtained from the Bureau of Indian Standards.

10 SAMPLING

10.1 Lot

All thermometers of the same type, in a singly



consignment and produced under similar conditions of manufacture shall constitute a lot.

**10.2** The number of thermometers to be tested shall depend on the size of the lot and shall be in accordance with Table 2. The lots shall be declared as conforming to the requirement of the specification, if the number of defectives is equal or less than the number given in col 4 of Table 2.

Table 2 Scale of Sampling (Clause 10.2)			
Sl No.	Number of Thermometers in the Lot	Sample Size	Acceptance Number
(1)	(2)	(3)	(4)
i)	91-50	20	1
ii)	151-280	32	2
iii)	281-500	50	3
iv)	501-1 200	80	5
v)	1 201 and above	125	7

ANNEX A

(Clause 7.2.1)

DETERMINATION OF THE MEAN DEPRESSION OF ZERO OF THERMOMETERS

**A-1** It is not possible to determine the depression of zero of clinical thermometers (mercury-in-glass, with the maximum indicating device) covered by this standard. Therefore, special test thermometers (*see A-2*) shall be manufactured from the glass being examined in order to conduct the necessary measurement.

**A-2** The test thermometers must meet the following requirements.

**A-2.1 Scale Range**

At least from  $\pm 3.0^{\circ}\text{C}$ .

**A-2.2 Scale Interval**

$0.02^{\circ}\text{C}$ ,  $0.05^{\circ}\text{C}$  or  $0.1^{\circ}\text{C}$ .

**A-2.3** The scale spacing must be at least 1.0 mm.

**A-2.4** The expansion chamber must be large enough to allow the thermometers to be heated to  $400^{\circ}\text{C}$  without damage.

**A-2.5** The thermometers must be properly stabilized by the manufacturer and must meet the requirements of the stabilization test (*see A-3*).

**A-3** The proper stabilization of each test thermometer must be tested in accordance with the following provisions.

**A-3.1** The thermometer is heated in a test bath (liquid bath or metal block type oven) from ambient temperature up to  $350 \pm 10^{\circ}\text{C}$  and kept at this temperature for at least 5 min. It is then cooled to  $50^{\circ}\text{C}$  in the test bath, which decreases in temperature by 10 to  $15^{\circ}\text{C/h}$ .

**A-3.2** When the thermometer has reached a temperature of  $50^{\circ}\text{C}$ , it is removed from the test bath

and its  $0^{\circ}\text{C}$  correction value ( $K_1$ ) is determined with the help of a zero point ( $0^{\circ}\text{C}$ ) ice bath, which consists of a Dewar flask filled with finely crushed ice covered over with water. The water used to make the ice and the water in which ice is submerged must be pure. Its electrical conductivity must not exceed  $10^{-3}\text{S.m}^{-1}$  at  $20^{\circ}\text{C}$ . The ice must be carefully tamped so that there are no air bubbles in the ice-water mixture. It must be compacted as much as possible both prior to measurement and periodically during measurement.

It is recommended that a water purifier, a refrigerator with ice trays and an ice crusher be employed for preparing the ice-water mixture.

**A-3.3** The thermometer is then heated a second time to  $350 \pm 10^{\circ}\text{C}$  in the test bath and kept at this temperature for 24 h. It is then cooled to  $50^{\circ}\text{C}$ , as before (*see A-3.1*).

**A-3.4** When the thermometer has reached a temperature of  $50^{\circ}\text{C}$ , it is removed from the test bath and its  $0^{\circ}\text{C}$  correction value ( $K_2$ ) is determined once more.

**A-3.5**  $K_2$  must not differ from  $K_1$  by more than  $0.15^{\circ}\text{C}$ . Thermometers, which do not meet this requirement, must not be used to determine the depression of zero.

**A-4** The mean depression zero is determined in accordance with the following provisions.

**A-4.1** At least three test thermometers must be used. They must be manufactured from the glass being tested, must have met the requirements of the stabilization test (*see A-3*), and not have been heated above the ambient temperature once value  $K_2$  has been determined (*see A-3.4*).

**A-4.2** Each of these thermometers must be tested at least three times in accordance with the provisions of A-4.2.1 to A-4.2.3.

**A-4.2.1** The thermometer is kept in a test bath at  $100 \pm 1.0^\circ\text{C}$  for 30 min. It is then removed from the bath and allowed to cool in air. While it is cooling to ambient temperature, its bulb must not come into contact with other objects.

**A-4.2.2** The  $0^\circ\text{C}$  correction of the thermometer is determined not later than 15 min after the thermometer has been removed from the test bath. The correction value obtained is designated by the symbol  $K_3$ .

**A-4.2.3** The thermometer is then kept for one week at a temperature between  $20^\circ\text{C}$  and  $25^\circ\text{C}$ . At the end of the week the  $0^\circ\text{C}$  correction is determined. This correction value is designated  $K_4$ . The procedures described in A-4.2.1 and A-4.2.2 are then repeated, and a  $0^\circ\text{C}$  correction value, designated  $K_5$ , is obtained.

**A-4.2.4** The procedures described in A-4.2.3 are repeated to obtain a series of  $n$  differences  $K_2 - K_3$ ,

$K_4 - K_5, K_{2n+1}$ . These are the values of the thermometer's depression of zero from the first, second and  $n$ -th series of measurements, respectively.

**A-4.2.5** When  $n$  series of measurements have been made with  $m$  test thermometers, the following expression is obtained for the mean depression of zero of these thermometers:

$$\frac{1}{mn} \sum_{i=1}^m \left[ \left( K_2^{(i)} - K_3^{(i)} + K_4^{(i)} - K_5^{(i)} + \dots + K_{2n}^{(i)} - K_{2n+1}^{(i)} \right) \right]$$

which must not exceed  $0.07^\circ\text{C}$  (see 7.2.2).

In accordance with the provisions of A-4.1 and A-4.2, the conditions  $m \geq 3$  and  $n \geq 3$  must be met for  $m$  and  $n$ , and the standard deviation of the mean depression of zero determined in accordance with the aforementioned provisions, must not exceed  $\pm 0.01^\circ\text{C}$ .

**A-4.2.6** If a more accurate value for the mean depression of zero is required, at least five series of measurements on at least five test thermometers must be carried out.

## ANNEX B

(Clause 7.3.2.1)

### TEST FOR HARDNESS OF MAXIMUM INDICATING DEVICE

#### B-1 APPARATUS

##### B-1.1 Centrifuge

A centrifuge with radial arms 15 cm each. Each arm shall be provided with a pocket for keeping one or more clinical thermometers. Speed of the centrifuge shall be either fixed or adjustable to 600 rpm.

NOTE — In general, centrifugal acceleration is  $4\pi^2 r N^2$  which reduces to  $r N^2 = 5\,472\,000$ , if  $r$  is in cm,  $N$  is revolutions per minute and the required acceleration is  $600\text{ m/s}^2$ , as specified in 7.3.2.1.

#### B-2 PROCEDURE

**B-2.1** Place the thermometers for some time in water at a temperature anywhere between  $42$  and  $43^\circ\text{C}$ .

**B-2.2** Then put them in the pockets of the centrifuge, bulbs facing outwards, that is, away from the axis of the centrifuge while in rotation.

**B-2.3** Let the centrifuge work steadily at its correct speed for 2 min. Then stop it.

**B-2.4** Take the thermometers out of the pockets and observe the mercury column.

**B-2.5** Thermometers shall be taken as having satisfied the requirement of this test if the mercury column rests below or at  $35^\circ\text{C}$  mark.

NOTE — It is necessary that the room temperature does not exceed  $34.5^\circ\text{C}$  during the test.

## ANNEX C

*(Clause 8.2.2)*

### TESTS FOR ACCURACY

#### C-1 APPARATUS

##### C-1.1 Constant Water Bath

Water bath should have constant temperature with auto cut-off and auto on temperature control device. It should have suitable mechanism to keep the water bath at constant temperature within  $\pm 0.05^{\circ}\text{C}$ .

##### C-1.2 Reference Thermometers

Calibrated thermometers having national traceability shall be used as reference thermometers. Calibrated

reference thermometer shall have range of  $35^{\circ}\text{C}$  to  $43^{\circ}\text{C}$  and least count  $0.05^{\circ}\text{C}$ .

#### C-2 PROCEDURE

**C-2.1** After preliminary check of the clinical thermometers, carry out the accuracy test in accordance with 6.2 of IS 6274 at  $37.0 \pm 0.5^{\circ}\text{C}$ ,  $39.0 \pm 0.5^{\circ}\text{C}$  and  $41.0 \pm 0.5^{\circ}\text{C}$ .

**C-2.2** The thermometers shall be considered to have passed this test, if the accuracy so determined lies within limits prescribed in 8.2.

**ANNEX D****(Foreword)****COMMITTEE COMPOSITION****Medical Instruments and Disposables Sectional Committee, CHD 35**

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## IS 3055 (Part 2) : 2004

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Top Syringe Manufacturing Company, Mumbai	SHRI K. J. SHANDILYA
University College of Medical Science and Guru Teg Bahadur Hospital, Delhi	DR (SHRIMATI) VIBHA TALWAR
BIS Directorate General	DR U. C. SRIVASTAVA, Director & Head (CHD) [Representing Director General ( <i>Ex-officio</i> )]
<i>Member Secretary</i> SHRI P. GHOSH Director (CHD), BIS	

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**Review of Indian Standards**

Amendments are issued to standards as the need arises on the basis of comments. Standards are also reviewed periodically; a standard along with amendments is reaffirmed when such review indicates that no changes are needed; if the review indicates that changes are needed, it is taken up for revision. Users of Indian Standards should ascertain that they are in possession of the latest amendments or edition by referring to the latest issue of 'BIS Catalogue' and 'Standards: Monthly Additions'.

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**Amendments Issued Since Publication**

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**BUREAU OF INDIAN STANDARDS**

**Headquarters :**

Manak Bhavan, 9 Bahadur Shah Zafar Marg, New Delhi 110 002  
Telephones : 2323 0131, 2323 33 75, 2323 9402

Telegrams : Manaksanstha  
(Common to all offices)

**Regional Offices :**

	Telephone
Central : Manak Bhavan, 9 Bahadur Shah Zafar Marg NEW DELHI 110 002	{ 2323 7617 2323 3841
Eastern : 1/14 C.I.T. Scheme VII M, V. I. P. Road, Kankurgachi KOLKATA 700 054	{ 2337 8499, 2337 8561 2337 8626, 2337 9120
Northern : SCO 335-336, Sector 34-A, CHANDIGARH 160 022	{ 60 3843 60 9285
Southern : C.I.T. Campus, IV Cross Road, CHENNAI 600 113	{ 2254 1216, 2254 1442 2254 2519, 2254 2315
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